IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

FLANDRO, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:13-cv-17027

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(Motions in Limine)

Pending before the court are the plaintiffs' Motion in Limine [ECF No. 110] and the defendant's Initial Motions in Limine [ECF No. 111].

This case resides in one of seven MDLs assigned to the court by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 19,000 of which are in the Boston Scientific Corporation ("BSC") MDL, MDL No. 2326.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011).

From time to time, the court seeks the assistance of the parties in completing

these tasks by asking the parties to focus on discrete, important, or more relevant matters. The court expected the parties to focus their motions in limine on matters possessing prejudice so potent it would be hard to dissipate with a curative instruction. Pretrial Order No. 142, at 1. Nevertheless, in some instances, the parties fret over matters both minimal and curable.

Other concerns also arise. Several of the requests concern evidence that *may* be presented. The court advised it would not offer advisory admissibility opinions, so the court declines to grant or deny requests of this sort. Pretrial Order No. 142, at 1. And some of the requests address expansive categories of evidence without concern for context. The court is concerned with content and context, and where neither is presented, the court concludes the matter will not be considered until trial.

To be frank, the parties practically ignored Pretrial Order No. 142 on more than one front. Now bound by bureaucratic requirements, the court must rule on evidentiary matters it advised the parties to avoid.

I. The Defendant's Initial Motions in Limine

The defendant filed a single Initial Motions in Limine [ECF No. 111], which includes arguments relating to nine distinct—yet not all unfamiliar—categories of evidence and arguments it seeks to exclude.

a. Motion to Preclude Evidence or Argument Regarding Fraud on the FDA or Alleged Misbranding

The plaintiffs have stated they will neither introduce evidence of nor present arguments about fraud on the FDA or alleged misbranding. Accordingly, the court **GRANTS** the defendant's Motion on this point.

b. Motion to Preclude Evidence or Argument Regarding BSC's Procurement of Polypropylene Resin Sourced in China

BSC asks the court to prohibit the plaintiff from presenting evidence related to a plot to procure polypropylene resin from China. BSC baldly asserts the device at issue here did not include resin procured from China. BSC further claims any probative value the evidence has is outweighed by the prejudice that would result from its presentation. But this evidence, the plaintiffs retort, inform their substantive and punitive damages claims.

The court agrees that this evidence is potentially relevant to the plaintiffs' substantive and punitive damages claims. However, any discussion of an alleged resin smuggling operation requires quite a digression from the issues central to this case. Time spent on explaining the intricacies of the smuggling scheme may detract from this case, transforming it from an individual-who-was-injured-by-a-product case into a corporate-cabals-and-international-intrigue case. For now, the scales seem close to even, counseling against exclusion. *See* Fed. R. Evid. 403 (noting exclusion is warranted if probative value is "substantially outweighed" by other considerations).

Despite the court's current assessment, an evidentiary ruling on this matter depends on the specific content introduced and the context in which it is introduced. So the court would be remiss at this time to weigh the overall substantive value against the overall prejudice related to this evidence in an effort to craft a blanket admissibility ruling. The court will wait to see the content and context before ruling on this matter. The court **RESERVES** judgment on this issue until trial.

c. Motion to Preclude Evidence or Argument Concerning BSC's Decisions

to Discontinue Selling Certain Mesh Products or Any Suggestion that its Products Were Recalled or Withdrawn

BSC asks the court to exclude evidence about its decisions to discontinue mesh products and product withdrawals or recalls. Decisions to discontinue, withdraw, or recall a product are likely subsequent remedial measures. These kinds of measures are not admissible to prove negligence, culpability, or product defects. Fed. R. Evid. 407. Accordingly, the court **GRANTS** the defendant's Motion on this point.[1]

d. Motion to Preclude Evidence or Argument that BSC Owed or Breached a Duty to Warn Plaintiff Directly

BSC asks the court to prohibit the plaintiffs from arguing BSC had or breached a duty to warn the plaintiffs about the risks associated with the devices at issue because the learned intermediary doctrine renders these arguments irrelevant. This doctrine focuses, in this context, on BSC's duty to warn physicians. *E.g.*, 63A Am. Jur. 2d *Prods. Liab.* § 1097 (2016). Any evidence that BSC owed or breached a duty to warn the plaintiffs directly is therefore irrelevant and subject to exclusion. Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."). The court **GRANTS** the defendant's Motion on this point. Some clarification is necessary though—this ruling only relates to evidence that BSC owed or breached a duty to the plaintiffs and does not address the admissibility of warnings that were or should have been provided to physicians.

[1] The plaintiffs respond that, in other trials, BSC has implied that certain mesh products are still in use, making this evidence relevant. But the court will not base its ruling here on BSC's conduct in other trials. That said, this issue may be revisited at trial if this evidence becomes admissible for another purpose. *See* Fed. R. Evid. 407 ("[T]he court may admit this evidence for another purpose, such as impeachment or—if disputed—providing ownership, control, or the feasibility of precautionary measures.").

e. Motion to Preclude Evidence or Argument that Pelvic Mesh Can Cause Complications Not Experienced by Plaintiff

BSC asks the court to exclude evidence of and to prohibit argument about medical complications allegedly caused by devices manufactured by BSC but not experienced by the plaintiffs. In general, other injuries are irrelevant because this case is about the plaintiff's injuries alone. *E.g.*, *Tyree v. Boston Sci. Corp.*, No. 2:12-cv-8633, 2014 WL 5445769, at *6 (S.D. W. Va. Oct. 22, 2014). But in the rare case, other complications and injuries may be relevant. This depends on content and context. So the court **RESERVES** judgment on this issue until trial. However, the court advises the parties to be mindful of the rule of relevancy and the prejudice that could be caused by such evidence when deciding what evidence they plan to present.

f. Motion to Preclude Evidence or Argument Concerning Lawsuits Against Other Manufacturers of Pelvic Mesh Devices

BSC asks the court to exclude evidence of and to prohibit argument about lawsuits against other manufacturers of pelvic mesh. Here—as in the other MDLs involving other mesh manufacturers—evidence of other lawsuits against other manufacturers is inadmissible. *E.g.*, *Tyree*, 2014 WL 5445769, at *7. Evidence of this variety is inadmissible under Rule 403 because its prejudicial effect outweighs its probative value. *E.g.*, *id.* ("Even assuming evidence about lawsuits brought against other manufacturers has some relevance to the present case, the relevance is dwarfed by the risk of unfair prejudice posed by requiring BSC to attest for lawsuits in which it was not involved."). Accordingly, the court **GRANTS** the defendant's Motion on this point.

g. Motion to Preclude Evidence or Argument Concerning Other Mesh Lawsuits, Investigations, Claims, Verdicts, and Trials Against BSC

BSC moves to preclude evidence and arguments about other lawsuits, claims, investigations, regulatory actions, or settlements involving any of BSC's mesh products. This category of evidence—like other categories focused on other cases, other manufacturers, other injuries, and the like—is inadmissible under Rule 403. Evidence of other proceedings against BSC will only confuse the jury, pulling its attention away from the instant proceeding, and is highly prejudicial to the defendant. *E.g.*, *Tyree*, 2014 WL 5445769, at *7–8. Therefore, the court **GRANTS** the defendant's Motion on this point.

h. Motion to Preclude Evidence or Argument Concerning Unrelated FDA Corporate Warning Letters and 483 Letters Pertaining to Cardiac Devices

The plaintiffs have stated they will neither introduce evidence of nor present arguments about 2006 corporate warning letters and FDA 483 letters concerning cardiac devices. Accordingly, the court **GRANTS** the defendant's Motion.

i. Motion to Preclude Evidence or Argument Regarding BSC's Designation of Documents as Confidential or Any Suggestion that BSC's Actions Were Improper or an Attempt to Keep Certain Documents Secret

Time after time, the court has ruled that whether a document is designated as confidential is entirely irrelevant. *E.g.*, *Tyree*, 2014 WL 5445769, at *9. The court will, as always, instruct the jury to disregard the confidentiality markings on documents presented at trial. The court **GRANTS** the defendant's Motion on this point.

II. Plaintiffs' Motion in Limine

In this case, the plaintiffs filed one Motion in Limine [ECF No. 110]. The plaintiffs ask the court to exclude evidence related to the FDA, including the FDA's 510(k) process, arguing it is impermissibly irrelevant and prejudicial under Federal Rules of Evidence 402 and 403.

In short, the 510(k) process "does not in any way denote official approval of [a] device." 21 C.F.R. § 807.97. The process is not focused on whether a device is safe; it is concerned with the devices equivalence to another device. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996). Because the process does not speak to the safety or efficacy of any product, whether BSC products were approved through this process is irrelevant. Even if the 510(k) process were relevant, the court would exclude this evidence under Rule 403. Any kernel of relevance is outweighed by "the very substantial dangers of misleading the jury and confusing the issues." *In re C. R. Bard*, 810 F.3d 913, 922 (4th Cir. 2016) (affirming the court's exclusion of 510(k) evidence).

Put simply, evidence of this sort is inadmissible and, in any event, does not survive a Rule 403 analysis. So the court **GRANTS** the plaintiffs' Motion on this point. The court will not belabor the point here, it has already done so on several occasions in this MDL and its sister MDLs. *E.g.*, *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754–56 (S.D. W. Va. 2014).

III. Conclusion

As outlined above, the court **GRANTS in part and RESERVES in part** the defendant's Initial Motions in Limine [ECF No. 111] and **GRANTS** the plaintiffs' Motion in Limine [ECF No. 110].

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 19, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE